

## REMARKS

The present amendment and arguments are submitted in response to an office action issued on July 29, 2010. The application contains claims 43, 48-50, 73-76, 79-90, 92 and 94-95. Claim 43 is amended herewith. Claims 44-47, 77-78, 91 and 93 are currently cancelled. Claims 94 - 97 are new.

The amendment to claim 43 and new claims 96-97 are supported at least by page 12, lines 21-27 and page 19, lines 5-14. New claims 94 and 95 contain features which are currently cancelled from claim 43.

### Drawings

The drawings stand objected to under 37 CFR 1.83(a) since they fail to show every feature of the invention specified in the claims. Before referring to the rejections specifically, applicants would like to emphasize that 37 CFR 1.83(a) requires that the drawings show all the features identified in the claims. However, 37 CFR 1.83(a) does not require claimed limitations to be shown in the drawings. Accordingly, the Examiner's rejections should be withdrawn.

Nevertheless, applicants will relate to the rejections raised by the Examiner. Some of the features indicated by the Examiner relate to claims which are cancelled in this response and are therefore not related to.

- "wherein the internal and external sheaths coextend at their distal ends, such that their distal ends extend to a same point" (claim 49). Applicants respectfully submit that this feature is shown at least in Fig. 9.

- "wherein the external and the internal sheath are connected to a proximal connector" (claim 79). Applicants previously argued that a proximal connector in the form of a proximal tube 110 is illustrated in Fig. 1A. The Examiner indicates that the sheaths are not shown connected to connector 110 in any form or manner. Applicants respectfully disagree and submit that at least external sheath 108 is shown connected to connector 110. It is inherent that the internal sheath is also connected to the connector. In any case, as the features (sheaths and

connector) are shown in the drawings, the limitations concerned thereto are not required to be shown there.

- "wherein the external sheath is sealed at its distal end" (Claim 81). Applicants respectfully submit that an example of a sealed distal end is shown in Fig. 1A, at the external sheath shown beneath nozzle 116.

### **Claim Objections**

Claim 93 is objected to since it is identical to claim 49. Claim 93 is cancelled herewith.

### **Claim Rejections 35 USC 112**

Claims 43, 48-50, 73-76, 79-90, 92 stand rejected under 35 USC 112 as failing to comply with the written description requirement since the recitation of "the sheathed probe" in claim 43 has insufficient antecedent basis. The recitation was removed from claim 43 and presented in new claim 94. The recitation was amended to "the sheath assembly" in claim 94 which finds antecedent basis in line 1 of claim 43.

### **Claim Rejections 35 USC 102**

Claim 43 is the only independent claim in the application. The Examiner provided 4 different anticipation rejections to claim 43. Before relating to each rejection specifically, applicants present the following argument for patentability of claim 43 over all of the cited art.

Claim 43 is amended and now reads:

*"A sheath assembly for a probe, comprising:  
an internal sheath configured to isolate a probe from body fluids; and  
an external sheath surrounding the internal sheath, the external sheath configured to define a channel for passing of fluids, tools or working tubes and the internal and external sheaths being connected to each other,*

*wherein the external sheath and the internal sheath are not coupled along their length,  
and*

*wherein the internal sheath is not affected when tools or working tubes are passed  
through the channel."*

Applicants submit that none of the cited art shows or even suggests the combination of a sheath assembly wherein the external and internal sheath are not coupled along their length and wherein the internal sheath is not affected when tools or working tubes are passed through the channel. The cited art either teaches either a rigid internal sheath to which the external sheath is attached along the length thereof, or an elastic internal sheath which is affected by forced that insert working tools through the channel.

Applicants have also added new claims 96 and 97 which further define the claimed features as follows:

96. *A sheath assembly according to claim 43, wherein the external sheath and the internal sheath are coupled at their distal ends only.*

97. *A sheath assembly according to claim 43, wherein the channel imparts an asymmetrical force on the internal sheath when tools or working tubes are passed through the channel.*

Applicants have removed from claim 43 limitations that were added in their previous response since they are not considered necessary for patentability of claim 43. The removed limitations are presented in new dependent claims 94 and 95.

Applicants will now refer to each of the rejections specifically.

Claims 43-45, 47, 49, 73-77, 79, 82-84 and 91-93 stand rejected under 35 USC 102(b) as being anticipated by Nakao et al. (US 5,217,001).

Applicants submit that Nakao fail to teach an internal sheath and an external sheath as recited in amended claim 43. The Examiner rejected claim 43 under the embodiment of Nakao shown in Figs. 7-10.

The external sheath of Nakao in the embodiments of Figs. 7-10 are a plurality of flexible webs which are attached along the length of the internal sheath and therefore do not meet the claim requirement of "wherein the external sheath and the internal sheath are not coupled along their length".

In addition, the inner sheath of Nakao is inflated to form a snug contact around the probe, see col. 8, lines 27-38. The flexible webs of Nakao are adapted to expand by forcibly inserting endoscopic surgical instruments, see col. 8, lines 49-55. Thus, undoubtedly, insertion of the surgical instruments by forcibly expanding the flexible webs also affects the internal sheath which is held by a pressured balloon, contrary to the requirements of claim 43.

Thus, claim 43 and its dependent claims are patentable over Nakao.

Claims 43, 43, 80, 85 and 90 stand rejected under 35 USC 102(b) as being unpatentable over Bacich et al. (US 5,749,889).

Applicants respectfully submit that Bacich fails to teach internal and external sheaths which are not coupled along their length as recited in claim 43.

As shown in Figs. 3 and 4 of Bacich, the internal and external sheath are coupled along their length by a split sheath 134.

Accordingly, applicants submit that claim 43 and its dependent claims are patentable over Bacich.

Claims 43, 48, 50, 78, 81 and 86 stand rejected under 35 USC 102(b) as being anticipated by Krasner et al. (US 4,676,228).

Applicants respectfully submit that Krasner fails to teach the features of claim 43.

The internal (46) and external sheath (18) of Krasner are coupled along their length, as shown in Fig. 3 for example and therefore do not meet the claimed feature of " wherein the external sheath and the internal sheath are not coupled along their length".

Claims 43 and 48 stand rejected under 35 USC 102(e) as being anticipated by Oneda et al. (US 6,461,294 herein referred Oneda1).

Applicants respectfully submit that Oneda1 fails to teach the features of claim 43.

The internal (103) and external sheath (300/400/500) of Oneda1 are coupled along their length, as shown in Figs. 3-5 and therefore do not meet the claimed feature of " wherein the external sheath and the internal sheath are not coupled along their length".

### **Claim Rejections 35 USC 103**

Claim 89 stands rejected under 35 USC 103(a) as being unpatentable over Silverstein in view of Oneda et al. (US 6,174,280 herein referred to as Oneda2).

Claim 89 depends on claim 43 and is patentable at least by virtue of its patentable parent claim.

### **Conclusion**

In view of the above amendments and arguments, applicants submit that independent claim 43 and dependent claims 43, 48-50, 73-76, 79-90, 92 and 94-97 are patentable over the cited art. Notice thereof is respectfully awaited.

Respectfully submitted,

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Date: November 29, 2010

### **Enclosures:**

- Petition for Extension (One Month)
- Request for Continued Examination (RCE)